

K203598 Omnichroma Flow BulkFeb 3, 2021
56 days to decisionK203598 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k203598/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Dec 9, 2020
Decision date	Feb 3, 2021
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tokuyama Dental Corporation
Location	Washington, DC, US
Contact	Keith A. Baritt
510(k) history	19 submissions · 19 cleared · 2003-2021

REGULATORY CONSULTANT

Consulting firm	Fish & Richardson, P.C.
Contact	Keith A. Baritt

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203598/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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